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10/563,278	10/06/2006	Jacques Abraini	Serie 6132	6401

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AIR LIQUIDE
Intellectual Property
2700 POST OAK BOULEVARD, SUITE 1800
HOUSTON, TX 77056

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,278	ABRAINI ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *31-44, 46-56* is/are pending in the application.

4a) Of the above claim(s) *31-42 and 50-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43,44,46-49 and 54-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/9/09 has been entered.

Claims 1-30, and 45 have been cancelled. Claims 31-42, and 50-53 are withdrawn. Claims 54-56 are new. Claims 43, 44, 46-49, and 54-56 are under examination.

Withdrawn rejections:

Applicant's amendments and arguments filed 3/9/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Claims 42, 43, 46 and 48 were rejected under 35 U.S.C. 102(a) as being anticipated by Homi et al. (Anesthesiology 2003, 99,876-881). Applicant has amended the claims and the rejection is withdrawn. Claims 43, 44 and 48 were rejected under 35 U.S.C. 102(b) as being anticipated by Mondain-Monval (US 4,820,258). Applicant has amended the claims and the rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43, 44, 46-49, and 54-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of drug addiction, does not reasonably provide enablement for *prevention and treatment of any and all drug addictions*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

Let the Examiner be clear: Applicant is not enabled for prevention and treatment of all drug addictions.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the

Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, that exposure to xenon or nitrous oxide immediately after pretreatment with d-amphetamine induces dose-dependent blocking of the sensitization process (specification page 10, lines 34-37 and specification page 11, lines 13-29, 35 through page 12, line 9). ***Thus Applicant appears to be enabled for those drug addictions that operate via the physiological pathway/ process described on pages 10-12 of the specification.*** However, Applicant is purporting to prevent and treat any and all drug addictions.

2) Nature of the invention

The nature of the invention is directed to a gaseous inhalable medicament comprising xenon and nitrous oxide for the treatment of drug addiction such as addiction to amphetamines and derivatives thereof, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances.

3) Relative level of skill possessed by one of ordinary skill in the art

MPEP 2141.03 states (in part), "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727, 167 LEd2d 705, 82 USPQ2d 1385, 1397 (2007). "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." Id. Office personnel may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ." Id. At 1396, 82

USPQ2d at 1396. The "hypothetical person having ordinary skill in the art' to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art." Ex parte Hiyamizu, 10 USPQ2d 1393, 1394 (Bd. Pat. App. & Inter. 1988) (The Board disagreed with the examiner's definition of one of ordinary skill in the art (a doctorate level engineer or scientist working at least 40 hours per week in semiconductor research or development), finding that the hypothetical person is not definable by way of credentials, and that the evidence in the application did not support the conclusion that such a person would require a doctorate or equivalent knowledge in science or engineering.). (emphasis added).

4) State of, or the amount of knowledge in, the prior art

The art teaches that administration of xenon to treat neurointoxications (Petzelt et al. (WO 00/53192). Jevtovic-Todorovic et al. teach a study designed to test the ability of nitrous oxide to protect neurons against excitotoxic.action of N-methyI-D-aspartate (reference C7 on the IDS submitted on 10/06/06) David et al. teach and suggest combining xenon and nitrous oxide to obtain optimal subcortical neuroprotection while minimizing the risk of adverse side effects and that the combination could be used in other brain diseases (reference C3 on the IDS submitted on 10/06/06).

5) Level or degree of predictability, or a lack thereof, in the art

The art teaches a laundry list of abused drugs and that there is no single treatment for all individuals with these **commonly abused drugs. (**commonly abused drugs; pages 1-6).

The MedlinePlus Medical Encyclopedia states that some people relapse after they have stopped using drugs and that drug educations programs may be helpful though none has proved effective in the long term for prevention of drug abuse and dependence (page 4 and 5 of 5).

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. The specification does not guide or provide direction for preventing and treating all forms of drug addiction.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to preventing or treating all forms of addiction. The specification is limited to describing exposure to xenon or nitrous oxide immediately after pretreatment with d-amphetamine induces dose-dependent blocking of the sensitization process (specification page 10, lines 34-37 and specification page 11, lines 13-29, 35 through page 12, line 9). However, nothing has been taught which would suggest that, for example, alcohol or tobacco or cocaine addiction can be treated.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to conduct a myriad number of experiments comprising administration of a gaseous mixture to individuals who have physiological addictions to a laundry list of drugs with the hopes that the composition will perform as instantly claimed. This is especially difficult when the art teaches that some people relapse after they have stopped

taking drugs. *While Applicant appears to be enabled for those drug addictions that operate via the process described on pages 10-12 of the specification, drugs that operate via a different biochemical pathway would not benefit from such treatment.* Essentially, one of ordinary skill in the art has to figure out how to do this themselves. As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to see if this invention is enabled.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable." (Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite: "amphetamines and derivatives thereof". Derivatives is indefinite because it is unclear how far one can theoretically make derivatized amphetamines and still retain function and therefore the structure of is unknown. The Examiner suggests removing the term "derivatives".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 43, 44, 46-49 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lecourt et al. (US 2002/0033174) in view of Petzelt et al. (WO 00/53192) and Jevtovic-Todorovic et al. (reference C7 on the IDS submitted on 10/06/06) and Brooks (US 5846556).

Please note that this rejection is only over the subject matter for which Applicant is enabled.

Applicant claims a gaseous inhalable medicament for the prevention or treatment of addiction, wherein the medicament comprises from 20-32% by volume of xenon and from 20-40% by volume of nitrous oxide.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Lecourt et al. teach an inhalable medicament intended for the treatment of pain with a therapeutically effective amount of a mixture of several gases chosen from helium, **oxygen**, nitrogen, **xenon**, hydrogen, carbon monoxide, carbon dioxide, argon, krypton, nitrogen monoxide, **nitrous oxide**, carbonated hydrocarbons and fluorocarbons (Abstract and claims 13 and 14). Therefore, it is the Examiner's position that all possible proportions of gases that are therapeutically effective are embraced by Lecourt et al.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, treating drug addiction wherein the addiction being treated is addiction to amphetamines and derivatives thereof, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Petzelt et al. teaches preparation of gaseous mixtures of xenon with 5 to 90% by volume xenon and further contains oxygen and/or nitrogen and/or air (Claims 12-15). Petzelt et al. suggest mixing xenon with other gases harmless for humans (page 6, middle of page). Petzelt et al. teach the use of the gas mixture for treating apoplexy (stroke) and craniocerebral trauma (claims 1, 4 and 8).

Jevtovic-Todorovic et al. teach a study designed to test the ability of nitrous oxide to protect neurons against excitotoxic.action of N-methyI-D-aspartate (Right column, page 460). Jevtovic-Todorovic et al. treated adult rats with various gas mixtures of nitrous oxide and oxygen ranging from 20%, 40%, 80%, 150% and 180% nitrous oxide, for example (Page 462, top left column and page 463, methods). Jevtovic-Todorovic et al. suggest that administration of nitrous oxide may provide neuroprotection against cerebral ischemic events that sometimes accompany surgery (Page 463, left column).

Brooks teaches compositions with 0-30 % nitrous oxide (column 2, lines 34-37).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Lecourt et al. is that Lecourt et al. do not expressly teach the instantly claimed amounts of xenon and nitrous oxide in the composition. This deficiency in Lecourt et al. is cured by the teachings of Petzelt et al., Brooks and Jevtovic-Todorovic et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Lecourt et al. with 20-32% xenon and from 20-40% nitrous oxide; or a composition of xenon and nitrous oxide of about 30%; or a composition from 10 to 20 % by volume xenon and from 45 to 50% of nitrous oxide or a volume proportion

of xenon of about 16% and a volume proportion of nitrous oxide of about 50%, as suggested by Petzelt et al., Brooks and Jevtovic-Todorovic et al.

One of ordinary skill in the art would have been motivated to do this because: 1) Lecourt et al. suggest mixtures of gases but only teaches a therapeutically effective amount and one of ordinary skill in the art would select xenon and nitrous oxide for mixing because the invention of Lecourt et al. is directed towards treating pain the anesthetic/analgesic gases nitrous oxide and xenon stand out amongst the other gases for that selection; and 2) the cited references teach a wide range of gas amounts to use and it is then merely routine optimization of those amounts to arrive at the instant invention. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant asserts that Lecourt uses at least one gas in combination with at least one active product whereas in the instant invention the medicament is the xenon and nitrous oxide. These arguments are not persuasive because the instant claims use open language which can allow for additional active agents. The treatment of drug addiction is intrinsic to the composition as discussed above. The secondary references provide guidance for the amount of gases to use in the composition of combined gases suggested by the primary reference which would have been known to one of ordinary skill in the art at the time of the instant invention absent unexpected results.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 47-49 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mondain-Monval (US 4,820,258).

Please note that this rejection is only over the subject matter for which Applicant is enabled.

Applicant claims a gaseous inhalable medicament for the prevention or treatment of drug addiction, wherein the medicament comprises from 10% to 20% by volume of xenon and from 45% to 50% of nitrous oxide.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Mondain-Monval teach gaseous mixtures containing from about 50 to 80% by volume nitrous oxide; at least about 20% by volume oxygen and an inert gas; xenon (Claims 1-5). Thus one of ordinary skill in the art can envision a gaseous mixture of **50% by volume** nitrous oxide; 20% by volume oxygen and **30 % by volume xenon**.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, treating drug addiction wherein the addiction being treated is addiction to amphetamines and derivatives thereof, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances, however, the intended use of the

claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Mondain-Monval is that Mondain-Monval do not expressly teach a composition comprising 10-20% by volume xenon and from 45-50% nitrous oxide; the volume proportion of xenon is about 16% and the volume proportion of nitrous oxide is about 50%; or 10-20% by volume xenon and from 45-50% nitrous oxide.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Mondain-Monval comprising 10-20% by volume xenon and from 45-50% nitrous oxide; the volume proportion of xenon is about 16% and the volume proportion of nitrous oxide is about 50%; or 10-20% by volume xenon and from 45-50% nitrous oxide, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Mondain-Monval already establish a composition with 50% nitrous oxide and at least 20% oxygen and an inert gas such as xenon. It is merely manipulation of the amounts suggested by Mondain-Monval to arrive at the instant invention in the absence of evidence to the contrary.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/

Examiner, Art Unit 1616